

## § 522.960

## 21 CFR Ch. I (4–1–01 Edition)

(B) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*, *P. multocida*, and *Haemophilus somnus*. For treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

(ii) *Control of disease—(A) Amount.* 40 milligrams per kilogram of body weight (6 milliliters per 100 pounds) as a single subcutaneous injection.

(B) *Indications for use.* For control of respiratory disease in cattle at high risk of developing bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*, *P. multocida*, and *Haemophilus somnus*.

(iii) *Limitations.* For intramuscular or subcutaneous use only. Do not inject more than 10 milliliters at each site. Injection should be given in the neck only. Do not slaughter within 28 days of last intramuscular treatment or within 38 days of subcutaneous treatment. Do not use in female dairy cattle 20 months of age or older. Use may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Not for use in cattle of breeding age. The effect of florfenicol on bovine reproductive performance, pregnancy, and lactation have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[61 FR 42383, Aug. 15, 1996, as amended at 63 FR 26981, May 15, 1998; 63 FR 41191, Aug. 3, 1998; 64 FR 5596, Feb. 4, 1999; 64 FR 9435, Feb. 26, 1999]

### § 522.960 Flumethasone implantation or injectable dosage forms.

#### § 522.960a Flumethasone suspension.

(a) *Chemical name.* 6 $\alpha$ ,9 $\alpha$ -Difluoro-11 $\beta$ ,17,21 - trihydroxy - 16 $\alpha$  - methylpregna - 1,4 - diene - 3,20 - dione.

(b) *Specifications.* Flumethasone suspension is sterile and each milliliter of the drug contains: 2 milligrams of flumethasone, 20 milligrams of propylene glycol, 9 milligrams of benzyl alcohol (as preservative), 8 milligrams of sodium chloride, 0.02 milligram of

polysorbate-80, 0.1 milligram of citric acid, and water for injection q.s.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is recommended in the various disease states involving synovial structures (joints) of horses where excessive synovial fluid of inflammatory origin is present and where permanent structural changes do not exist. Such conditions include arthritis, carpalis, and osselets.

(2) The drug is administered intraarticularly at a dosage level of 6 to 10 milligrams per injection. The dosage level is dependent upon the size of the involved synovial structure and the degree of severity of the condition under treatment. The dosage is limited to a single injection per week in any one synovial structure.

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally and parenterally to animals during the last trimester of pregnancy may induce the first stage of parturition and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. The drug is not to be used in horses intended for slaughter for food purposes.

(4) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975. Redesignated at 44 FR 16011, Mar. 16, 1979, as amended at 61 FR 5506, Feb. 13, 1996]

#### § 522.960b Flumethasone acetate injection.

(a) *Chemical name.* 6- $\alpha$ ,9- $\alpha$ -difluoro - 16 -  $\alpha$  - methylprednisolone 21-acetate.

(b) *Specifications.* Flumethasone injection is sterile and contains per cubic centimeter: 2 milligrams of flumethasone acetate; 20 milligrams of propylene glycol; 9 milligrams of benzyl alcohol (as preservative); 8 milligrams of sodium chloride; 1 milligram of polysorbate 80; 0.1 milligram of citric acid; water for injection q.s.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is recommended in certain acute and chronic canine dermatoses of varying etiology to help control the pruritus, irritation,